4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, and 522

[Docket No. FDA-2012-N-0002]

New Animal Drugs; Cefpodoxime; Meloxicam

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during December 2012. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect approval actions for several original ANADAs during December 2012, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain these documents at the Center for Veterinary Medicine FOIA Electronic Reading Room: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm.

Table 1.--Original ANADAs Approved During December 2012

NADA/ANADA	Sponsor	New Animal Drug Product Name	Action	21 CFR Section	FOIA Summary	NEPA Review
200-485	Accord Healthcare, Inc., 1009 Slater Rd., suite 210-B, Durham, NC 27703	Meloxicam Injection	Original approval as a generic copy of NADA 141-219	522.1367	yes	CE[1]
200-491	Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland	LOXICOM (meloxicam) Solution for Injection	Original approval as a generic copy of NADA 141-219	522.1367	yes	CE[1]
200-543	Putney, Inc., 400 Congress St., suite 200, Portland, ME 04101	Cefpodoxime Proxetil Tablets	Original approval as a generic copy of NADA 141-232.	520.370	yes	CE[1]

[1]The Agency has determined under 21 CFR 25.33 that this action is categorically excluded (CE) from the requirement to submit an environmental assessment or an environmental impact statement because it is of a type that does not individually or cumulatively have a significant effect on the human environment.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520 and 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, and 522 are amended as follows:

PART 510--NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

2. In § 510.600, in the table in paragraph (c)(1), alphabetically add an entry for "Accord Healthcare, Inc." and revise the entry for "Jurox Pty. Ltd."; and in the table in paragraph (c)(2), numerically add an entry for "016729" and revise the entry for "049480" to read as follows:

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Accord Healthcare, Inc., 1009 Slater Rd., suite 210-B, Durham, NC 27703	016729
* * * * *	

Jurox Pty. Ltd., 85 Gardiner St., Rutherford, NSW 2320, Australia	049480
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
016729	Accord Healthcare, Inc., 1009 Slater Rd., suite 210-B, Durham, NC 27703
* * * * *	
049480	Jurox Pty. Ltd., 85 Gardiner St., Rutherford, NSW 2320, Australia
* * * * *	

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.370 [Amended]

4. In paragraph (b) of § 520.370, remove “No. 000009” and in its place add “Nos. 000009 and 026637”.

PART 522--IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

5. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.1367 [Amended]

6. In paragraph (b) of § 522.1367, remove “No. 000010” and in its place add “Nos. 000010, 016729, and 055529”.

Dated: January 22, 2013.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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